

Detachable Inflatable Sheath



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Detachable Inflatable Sheath

- Key features for pre-deployment stent security
 - Stent and stent edges will not catch while SDS is advanced through lesion or previously deployed stent
 - No stent movement while advancing through difficult lesions
 - Pullback into non-coaxial guide
 - No compromise to deliverability
 - Device can be integrated into current balloon inflatable SDS platforms
 - Device is E-beam compatible

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Design Concept

- Elastomeric sheath attached over SDS
- Low pressure inflation
- Sheath ruptures and retracts before stent edges expand
- Sheath rupture allows deployment of stent

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Design Concept

- Attach sheath over SDS
 - Score → Proximal seal → Stretch → Distal seal

Distal

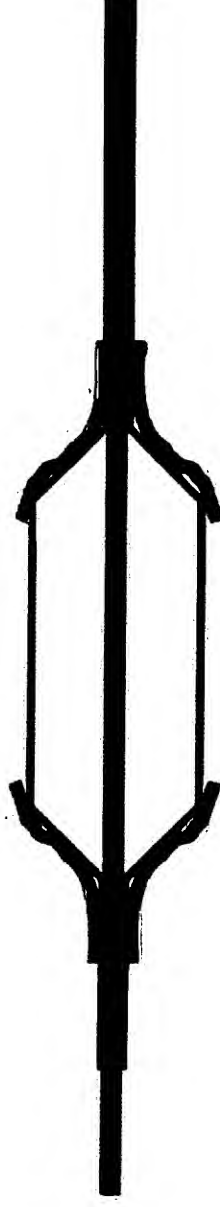
Proximal

Before
Inflation



Sheath pulls back at perforated edges

During
Inflation



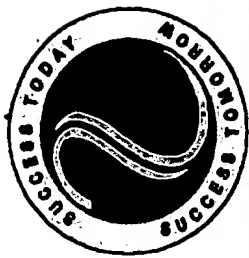
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Detachable Inflatable Sheath

- 5 mil thick sheath on 3.0 x 18 Duet
 - Pre-deployment profile 0.051"
 - Retraction at 2 atm
- Perforation



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Detachable Inflatable Sheath

- Increased stent security over current SDS platforms
- Key distinctions and features
 - Elastic, compliant sheath does not interfere with balloon inflation
 - Simple, inexpensive modification to SDS platforms
 - Readily manufacturable; minimal added development time
 - Minimal added profile and bulk
 - Complete protection over entire length of stent and stent edges
 - No added preparation or procedural time for interventionalist



Detachable Inflatable Sheath

- Recommendations for transfer to production
 - Optimize sheath rupture pressure
 - HPP to further reduce profile
 - Reduce sheath thickness
 - Optimize retraction
 - Separate lumen could allow sheath retraction prior to crossing lesion

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